K 003154

JAN - 5 2001

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
7992 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: October 1, 2000

807.92(a)(2)

Trade Name: MIZAR / Basis BE / Sandman Digital

Common Name: Physiological Signal Amplifier

Classification Name(s): Physiological Signal Amplifier

Classification Number: 84GWL

807.92(a)(3)

Predicate Device(s)

Artisan	Medcare Diagnostics	K992283

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary
MIZAR Amplifier
EB Neuro, S.p.A.

807.92(a)(5)

Intended Use(s)

The MIZAR Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

EB Neuro. S.P.A.
c/o Ms. Colleen J. Hittle
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K003154
Trade Name: MIZAR/Basis BE/Sandman Digital
Regulatory Class: II
Product Code: GWL
Dated: October 5, 2000
Received: October 10, 2000

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Applicant: EB Neuro, S.p.A.

510(k) Number (if known): K 003154

Device Name: MIZAR / Basis BE / Sandman Digital

Indications For Use:

The MIZAR Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysmnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** Over The Counter _____

(Per 21 CFR, 801.109)

(Optional Format 1-2-96)

Miriam C Provost for
(Division Sign-Off) C. Witten
Division of General Restorative Devices
510(k) Number K003154